

CLAIMS

1. A combination comprising
  - (i) 4-[[4-[[4-(2-cyanoethenyl)-2,6-dimethylphenyl]-amino]-2-pyrimidinyl]-amino]-benzonitrile, also named TMC278, or a stereoisomeric form thereof; or a pharmaceutically acceptable salt thereof; or a prodrug thereof; and
  - (ii) a nucleoside reverse transcriptase inhibitor and/or a nucleotide reverse transcriptase inhibitor; wherein TMC278 and the nucleotide reverse transcriptase inhibitor and the nucleoside reverse transcriptase inhibitor are therapeutically effective HIV inhibitors at a dose that can be administered once daily.
- 10 2. The combination according to claim 1 comprising
  - (i) TMC278, or a stereoisomeric form thereof; or a pharmaceutically acceptable salt thereof; or a prodrug thereof; and
  - (ii) a nucleoside reverse transcriptase inhibitor; wherein TMC278 and the nucleoside reverse transcriptase inhibitor are therapeutically effective HIV inhibitors at a dose that can be administered once daily.
- 15 3. The combination according to claim 1 comprising
  - (i) TMC278, or a stereoisomeric form thereof; or a pharmaceutically acceptable salt thereof; or a prodrug thereof; and
  - (ii) a nucleotide reverse transcriptase inhibitor; wherein TMC278 and the nucleotide reverse transcriptase inhibitor are therapeutically effective HIV inhibitors at a dose that can be administered once daily.
- 20 4. The combination according to claim 1 comprising
  - (i) TMC278, or a stereoisomeric form thereof; or a pharmaceutically acceptable salt thereof; or a prodrug thereof; and
  - (ii) a nucleotide reverse transcriptase inhibitor; and
  - (iii) a nucleotide reverse transcriptase inhibitor; wherein TMC278 and the nucleotide reverse transcriptase inhibitor and the nucleoside reverse transcriptase inhibitor are therapeutically effective HIV inhibitors at a dose that can be administered once daily.
- 25 5. The combination according to claim 1 comprising
  - (i) TMC278, or a stereoisomeric form thereof; or a pharmaceutically acceptable salt thereof; or a prodrug thereof; and
  - (ii) a nucleoside reverse transcriptase inhibitor; and
  - (iii) a second nucleoside reverse transcriptase inhibitor other than the nucleoside

reverse transcriptase inhibitor of (ii) ; wherein TMC278 and the nucleoside reverse transcriptase inhibitors are therapeutically effective HIV inhibitors at a dose that can be administered once daily.

6. The combination according to any of claims 1 – 5, wherein TMC278 occurs in its  
5 E-isomeric form.
7. The combination according to any of claims 1 – 6, wherein the nucleotide reverse transcriptase inhibitor and/or the nucleoside reverse transcriptase inhibitor or inhibitors select mutations in the reverse transcriptase that do not cause resistance to TMC278.
- 10 8. The combination according to any one of claims 1 to 7 wherein the nucleotide reverse transcriptase inhibitor is tenofovir or its prodrug tenofovir disoproxil fumarate.
9. The combination according to any one of claims 1 to 7 wherein the nucleoside reverse transcriptase inhibitor is emtricitabine, racemic FTC, lamivudine (also  
15 named 3TC), abacavir or a pharmaceutically acceptable salt thereof.
10. The combination according to any one of claims 1 to 7 wherein the nucleoside reverse transcriptase inhibitor is emtricitabine.
11. The combination according to any one of claims 1 to 7 wherein the combination comprises  
20 (i) TMC278 or a pharmaceutically acceptable salt, and  
(ii) tenofovir or its prodrug tenofovir disoproxil fumarate, and  
(iii) emtricitabine.
12. The combination according to any one of claims 1 to 7 wherein the nucleoside reverse transcriptase inhibitor is lamivudine.
- 25 13. The combination according to claim 8 wherein the combination comprises  
(i) TMC278 or a pharmaceutically acceptable salt, and  
(ii) tenofovir or its prodrug tenofovir disoproxil fumarate, and  
(iii) lamivudine.
14. The combination according to any one of claims 1 to 7 wherein the nucleoside  
30 reverse transcriptase inhibitor is abacavir or a pharmaceutically acceptable salt thereof.

15. The combination according to claim 14 wherein the combination comprises
  - (i) TMC278 or a pharmaceutically acceptable salt, and
  - (ii) tenofovir or its prodrug tenofovir disoproxil fumarate, and
  - (iii) abacavir or a pharmaceutically acceptable salt thereof.
- 5     16. The combination according to any one of claims 1 to 7 wherein the combination comprises
  - (i) TMC278 or a pharmaceutically acceptable salt, and
  - (ii) lamivudine, and
  - (iii) emtricitabine.
- 10    17. The combination according to any one of claims 1 to 7 wherein the combination comprises
  - (i) TMC278 or a pharmaceutically acceptable salt, and
  - (ii) abacavir, or a pharmaceutically acceptable salt thereof; and
  - (iii) emtricitabine.
- 15    18. The combination according to any one of claims 1 to 7 wherein the combination comprises
  - (i) TMC278 or a pharmaceutically acceptable salt, and
  - (ii) lamivudine, and
  - (iii) abacavir, or a pharmaceutically acceptable salt thereof.
- 20    19. The combination according to any one of claims 1 to 18 wherein weight ratio of each couple of components of the triple combination taken on a daily basis may vary in a range from 1/4 to 4/1.
- 25    20. A product containing a combination as claimed in any of claims 1 to 19 as a combined preparation for simultaneous, separate or sequential use against HIV infection.
21. A pharmaceutical formulation comprising a pharmaceutically acceptable carrier and a combination as claimed in any of claims 1 to 18.
- 30    22. The formulation of claim 21 comprising as active ingredients (i) TMC278 or its stereoisomeric form or pharmaceutically acceptable salt or its prodrug, and (ii) a nucleoside reverse transcriptase inhibitor, and (iii) a nucleotide reverse transcriptase inhibitor.
23. A combination as claimed in any one of claims 1 to 18 for use as a medicine.

24. Use of a combination as claimed in any one of claims 1 to 18 for the manufacture of a medicament for the prevention of HIV infection or transmission via sexual intercourse or related intimate contact between partners.